

## **REMARKS**

Claim 1 has been amended to recite the ratio range of beta glucan to lactoferrin contained in the composition and the specific form of the composition. Additionally, claims 1 and 16 have been amended to recite preferred concentration ranges of beta glucan and lactoferrin contained in the composition, and claims 17-18 have been amended to recite a preferred concentration of lactoferrin contained in the composition.

Support for the amendments can be found in Example 1 of the instant application, wherein 20 parts of beta glucan and 10 parts of bovine lactoferrin were placed in a mixer for preparation of a lozenge (i.e., composition in a mucosal delivery format) and in Example 2, wherein 20 parts of beta glucan and 10 parts of bovine lactoferrin were placed in a mixer for preparation of a gelatin capsule (i.e., composition in an encapsulated form). Support can further be found in Examples 3 and 4, wherein lozenges containing 20 mg beta glucan and 10 mg lactoferrin were administered to the patients. These exemplary formulations, either in a mucosal delivery format or in an encapsulated form, all contain beta glucan and lactoferrin in the ratio of 2:1.

As described on page 3, paragraph [0022] of the instant application (US 2002/0054917), mucosal delivery in the mouth is preferred over the gastric delivery of lactoferrin. Accordingly, gastric delivery in the form of an enteral feed preparation or the swallowing of a capsule requires approximately 150% of the amount of lactoferrin that could be delivered directly into the mouth. That is, for a composition in an encapsulated form, 50% more lactoferrin is required compared to a composition in a mucosal delivery format. In view of this, if a composition in a mucosal delivery format contains beta glucan and lactoferrin in a ratio of 2:1 (*See* Examples 1, 3 and 4), a

composition in an encapsulated form would contain beta glucan and lactoferrin in a ratio of 2:(1x150%), i.e., 2:1.5. If a composition in an encapsulated form contains beta glucan and lactoferrin in a ratio of 2:1 (*See* Example 2), a composition in a mucosal delivery format would contain beta glucan and lactoferrin in a ratio of 2:(1/150%), i.e., 2:2/3 (or about 2:0.7). The ratio range of the beta glucan and lactoferrin contained in the composition as claimed in claim 1 would be from about 2:1.5 to about 2:0.7. No new matter is introduced.

Regarding the preferred concentration range of beta glucan and lactoferrin contained in the compositions as claimed, Applicant submits that the support can be found in original claims 10 and 11, wherein the concentration range of about 0.25 weight percent to about 2.5 weight percent for lactoferrin and the concentration range of about 1 weight percent to about 10 weight percent for beta glucan were originally claimed. No new matter is introduced.

Claims 7, 10 and 11 have been cancelled in view of the above amendments.

Claims 2, 4 and 19-24 were previously cancelled.

Additionally, Applicant has renumbered misnumbered claims 19-33 from the Preliminary Amendment filed April 19, 2005 as 25-39 as requested by the Examiner. The renumbered claims 25-39 have now been withdrawn from the present amendments.

As amended, claims 1, 3, 5-6, 8-9 and 12-18 are pending in the present case.

## CONCLUSION

This preliminary amendment is accompanied by a Request for Continued Examination (RCE) and a petition for 2-month extension of time. The Commissioner is authorized to charge Howrey LLP Deposit Account No. 01-2508/13479.0002.CPUS01 for the RCE filing fee (\$395) and petition fee (\$225). Should any additional fees be required for any reason in connection with this paper, the Commissioner is authorized to deduct said fees from the same deposit account.

The Examiner is invited to contact the undersigned agent at (713) 787-1512 with any comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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